

Exhibit 49

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.

Civil Action No. 07-10248-PBS

Exhibit to the August 28, 2009 Declaration of James J. Fauci In Opposition To
Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc.
Local Rule 56.1 Statement of Undisputed Material Facts
in Support of Their Motion For Summary Judgment

From: KING,JIM MK BIPUS [BIPUS/CORP1/JIMKING]
Sent: Monday, April 07, 1997 3:16 PM
To: WATERER, JUDY ROXUS
Subject: Attached Draft

Judy:

I started trying to write the future status of RLI's pricing procedures in light of the litigation probabilities, and I got stumped after just a few lines....even those few lines are not correct. I wonder if I might ask you to take a crack at some verbiage that gives some insight to RLI's future.

Thanks

Jim K



PRICING.DOC

PRICING COMMITTEE

DRAFT

April 7, 1997

OBJECTIVE:

Redacted review BIPIs/RLI's current pricing and customers; tender a proposal for future models regarding class of trade and pricing;

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BIPI BACKGROUND:

BIPI places customers in four broad classifications: wholesalers, non-profit hospitals, city, county, state institutions, and the federal government. This classification was established quite some time ago, and although once may have been useful for financial purposes, it no longer describes the plethora of accounts that have evolved since its inception. In the recent past, new distribution channels have appeared and some have thrived. In addition, some of BIPI's traditional accounts have diversified and entered multiple distribution channels. A listing of potential accounts today is lengthy and their competitive structure is still developing.

Prices generally range from "Wholesale Acquisition Cost" (WAC) which is the price wholesalers pay for BIPI drugs, to some discount of prices using WAC as a standard. WAC is the highest price paid by customers to whom BIPI actually sells merchandise. A host of other customers: hospitals, nursing homes, nursing home providers, home healthcare agencies, and home healthcare distributors generally receive prices at or below the WAC for BIPI drugs. These prices range from 1 or 2% below WAC to rather significant discounts for few account classes. Balancing all price lowering plans for both BIPI and RLI is the omnipresent OBRA legislation which mandates a tax, in the form of Medicaid rebates, based on the Average Manufacturer's Price (AMP) for each drug. BIPI has been careful to limit price discounts to agencies that are not exempt from inclusion in the AMP formula to 15% or less. Standing alone are two separate classes whose prices are exempt from Medicaid rebates: the Veterans Administration/Defense Personnel Support Centers and the Public Health Service (PHS). PHS prices are federally mandated by a formula and are very low. The federal government hospitals "VA and DPSC" generally have low prices, because it has been traditional to sell to the government at low prices. Both these classes are exempt from Medicaid liabilities.

RLI BACKGROUND:

Products available from Roxane Labs can be categorized into one of three general classifications: branded sole-source, specialty, and multi-source generics. Each product within these categories is assigned pricing reflective of its market position and degree of competition. For every product, a "List Direct" price represents the highest price and it is used as suggested retail. For NWDA wholesalers, a catalog price discounted from List price is available as "Wholesale Acquisition Cost". Contract prices are developed using WAC as a standard.

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Each item in the Roxane product line may be offered under a “protective price agreement” for various timeframes. The complex mix of items, customer types, “i.e.: classes of trade”, annual usage commitments, pricing to “meet competition”, and accounts’ experience in contracting leads to many pricing strategies. Having a mix of branded sole-source, specialty, and multi-source generics gives RLI the opportunity to craft agreements using all these items in unique ways to gain and protect Roxane product market share.

Roxane currently extends pricing agreements to groups and/or individual facilities representing the following healthcare provider concerns: hospitals, long-term care facilities, and/or providers, HMOs, closed-door managed care pharmacies, independent retail pharmacies, warehousing and non-warehousing retail chain drugstores, surgical care centers, clinics, substance abuse clinics, out-patient pharmacies, city/count/state agencies, federal facilities, physicians offices, integrated healthcare, home healthcare.

Discounts for products can range from WAC to significant discounts from WAC based upon competitive market conditions. All contract groups are assigned a Significance Code which indicates market conditions similarity with “like” customers.

Product pricing for VA/DOD/PHS federal programs following either mandated formula pricing, “best pricing”, or AMP discounted pricing formulas. Pricing given to these customers is exempt from Medicaid liability

***The following section on [Redacted] was provided by Boehringer counsel at the request of the Pricing Committee.**

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BIPI/RLI FUTURE STATUS:

It is clear that "class of trade" designations have become obsolete due to the change in nature of distribution patterns and the different structures of purchasers and other participants in the healthcare system. Attention needs to be paid by BIPI/RLI to which customers compete with which customers and price our products in a similar fashion to each of these competitive classes. We have prepared three appendices which describe what we believe are the three major classes of entities which from time to time may compete. However, there are permutations of each class that must clearly be known to all operational contracting entities before entering into agreements.

Basically, there are rules which should be understood and followed:

1. Sales of the same products to competing customers should be at the same price.
2. If the sales of the products are at different prices, the differences in prices cannot be based on the class of trade or the size of the customer.
3. Differences in prices can be based on the need to meet, but not beat, documented competition, and in certain limited situations, on differences in functions or services performed.
4. If we give discounts or promotional allowances to customers, generally these discounts/promotional allowances must be made known and available to all competing customers.
5. We cannot establish criteria which make discounts/promotional allowances available to large customers, but exclude small companies competing with the large purchasers.

BIPI:

BIPI is placed reasonably well to deal with the market share commitments based on our history with managed care operations. We have generally stayed away from volume-based discounting and given discounts to entities based on those entity's abilities to constrain the use of our drugs. They have generally taken the form of market share rebate contracts. Therefore, our system of contracting would be able to handle demands from retail organizations that demand "marketshare" contracting.

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An issue which needs to be addressed is "who is in control of pricing?" We have marketing (eg: Product Managers), Managed Care, Sales, and Contracting. All these entities involve themselves in pricing decisions, and not all are aware enough of the laws, the litigation mandates, and customer permutations. In addition, at various times, each entity has been responsible for pricing to some customer. This will be addressed in the "Recommendations" section.

RLI

A significant part of RLI's business is multi-source generics and specialty (pain) products, which are also generic in nature. The pricing structure for generics is much more complex and competitive than branded sole-source drugs. Market share contracting is not popular in the generic field and it is unclear how the litigation results will affect generics. RLI avers that customers of any classification can get discount prices, if they perform warehousing functions, keep out other generics.

RECOMMENDATIONS:

1. Redacted
2. The separate entities of RLS and BIPI do not appear too separate to people outside our corporation. Therefore, it is important to regularly convene the above committee to ensure that pricing issues are squared away with both companies. This is especially important when bundling products together, selling a multisource generic of one of BIPIs branded products, etc.
3. The attached algorithm should be shared with all people involved in the pricing process as the blueprint for pricing decisions.

PRICING ALGORITHM:

- Opportunity to offer price
- With whom does the customer compete? Similar prices & terms to competing customers.
- Will the price create a new “best price”?
- Will the price breach a “favored customer” clause in another contract?
- Does the customer agree to have an “own use” certificate?
- Does the customer agree to contract language representing that they meet the conditions for one of the safe harbor provisions of the federal anti-kickback statute and performance of the contract will not violate the provisions of the anti-kickback statute?
- Does the price meet **documented** competition?